September 3, 2004

Burkholderia cepacia Recovery from Intensive Care Unit Patients

Dear Colleagues:

In August 2004, the Texas Department of Health received reports of *Burkholderia cepacia* recovery from respiratory samples of 13 intensive care unit patients on mechanical ventilation at one hospital in Texas from April to August 2004. None of the patients had cystic fibrosis, a common risk factor for recovery of *B. cepacia*. Use of a sublingual probe to monitor tissue carbon dioxide levels in nearly all of the patients was identified as a risk factor. The probe, an SLS-1Sublingual Sensor, part of the Nellcor®CapnoProbe™ Sublingual System (model N-80 monitor), is an FDA-regulated medical device. The devices are labeled as nonsterile and are intended for disposal after a single use.

Subsequent culture demonstrated *B. cepacia* and other GNRs in the buffered saline solution of at least two lots of intact product; the *B. cepacia* recovered was indistinguishable from that recovered from some patients on pulsed field electrophoresis analysis. Investigation is ongoing into reports from Texas and California of *B. cepacia* and other GNRs that might be associated with use of these probes. The manufacturer has issued a voluntary recall of all SLS-1 Sublingual Sensors. Unused probes should be returned to the manufacturer (Nellcor Technical Services department at 800-635-5267, option 3).

It is unclear from published reports if recovery of this organism represents infection or colonization, but clinicians should be aware that patients who have been exposed to these probes may have been exposed to *B. cepacia* and other GNRs. Clinical microbiology laboratories recovering *B. cepacia* should notify the Bureau of Laboratories and hold the organism for possible submission. Health care facilities are encouraged to report any events not reported under the mandatory process through FDA's voluntary reporting program (http://www.fda.gov/cdrh/mdr/index.html or phone 800-FDA-1088). Please share this information with your hospital colleagues.

James Rudrik, Ph.D.
Microbiology
517-335-9641
rudrikj@michigan.gov